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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,681	08/18/2003	Orville G. Kolterman	254/057CON	4614

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EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,681	KOLTERMAN ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-69* is/are pending in the application.

4a) Of the above claim(s) *31-37 and 60-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-30 and 38-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 24-69 are currently pending.

Claims 24-30 and 38-59 are under consideration.

Claims 31-37 and 60-69 are withdrawn from consideration as being directed to a nonelected invention.

Sequence Rules

Applicant's Raw Sequence Listing (CRF) has been received and entered.

Election/Restriction

Applicant's election with traverse of 25,28,29 tri-pro human amylin as the elected species in the correspondence dated 10/29/04 is acknowledged. The traversal is on the ground(s) that there is no burden to additionally examine Group II (sic Group III) since "the action of reducing gastric motility or delaying gastric emptying would be a factor in modulating postprandial blood glucose. This is not found persuasive for the reasons provided in the restriction/election requirement (e.g. on pages 2-3) that the methods are patentably distinct and require separately burdensome searches e.g. by addressing different disease states, classification and subject matter leading to different bibliographic and classification searches.

Applicant's further election of 25, 28,29 Pro H-amylin as the elected species in the reply filed on 10/29/04 is acknowledged; which reads on claims 24-30 and 38-59. Because applicant did not distinctly and specifically point out the supposed errors in the

restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, this requirement is still deemed proper and is therefore made FINAL.

Specification

1. The disclosure is objected to because of the following informalities:

2. On page 22, line 15+ (also page 30 etc), applicant "improperly" incorporates by reference amylin agonist analogs disclosed in WPI 182488. The amylin agonists incorporated by reference address claimed subject matter which directly bears on issues of enablement and/or description under 35 USC 112, first paragraph. The incorporation of *essential material* in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: incorporate essential subject matter necessary to provide support for the presently claimed invention should be inserted in the specification; and if necesssary a substitute specification must be submitted.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-30 and 41-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (NEW MATTER REJECTION).

The presently claimed subgenus of amylin agonist analogues (and corresponding use thereof) as defined by the presently claimed invention (e.g. A1-Z as defined and wherein one or more are D-amino acids) are not described in the specification; nor has applicant provided an indication where this subgenus is supported. The specification (e.g. pages 28-31 and 42) fails to provide sufficient support for the presently claimed subgenus and proviso relating thereto (D containing amylin analogues).

Additionally, with regard to newly added claims 56-59, the new proviso (a)-(f) which states that "then one or more of any of A1 to M1 is **not an L-amino** acid and Z is not amino" (emphasis provided) lacks specification support for the scope of amino acids encompassed by this terminology encompassing D-amino acids *and beyond*.

Applicant must provide evidence of how the presently claimed invention is supported or cancel the new matter.

Claims 24 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (Lack of Written Description).

It is first noted that written description is legally distinct from enablement: "Although the two concepts of are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures the that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention." See 1242 OG 169 (January 30, 2001) citing *University of California v. Eli Lilly & Co.*

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

The present claims are directed to a method of reducing or moderating a postprandial rise in plasma glucose in a mammal comprising administering to said mammal an amylin or an amylin agonist (e.g. claim 24).

Accordingly, the presently claimed invention is broadly directed to the therapeutic use of "amylin agonists" including "amylin agonist analogues" in any "subject". The specification (e.g. page 22) broadly defines "amylin agonists" as "compounds which mimic the effects of amylin"; and "amylin agonist analogues" as "derivatives of an amylin which act as amylin agonists, It is noted that no structure limitation appears to limit what constitutes an "amylin agonist". Additionally, the term "amylin agonist analogue" is defined as "derivatives" of an amylin which act as "amylin agonists" by a hypothesized "direct/indirect" interaction with amyln receptors or other receptors to which amylin itself may interact. No disclosure of particular receptors or specific functions are disclosed. Accordingly, the amylin analogue definition fails to define the types of derivations of amylin encompassed by the definition nor is there any defined limits with regard to function which is necessary to satisfy the amylin agonist analogue. Further, method claims directed to "a subject" broadly encompass any animal possessing a GI tract; although the specification speak of only murine, canine and human species.

The pharmacological and pharmacokinetic properties of amylin have not been extensively characterize, and are therefore difficult to predict. For example, although amylin shares considerable sequence homology with CGRP's (and to a lesser degree with insulin, relaxins and IGF) its physiological function appears to be distinct from that of the other peptides. Although some aspects of amylin function are accepted in the art,

e.g. inhibition of glycogen syntheses and inhibition of gastric secretion, others are not well understood. Additionally, the receptors to which amylin directly or indirectly interacts with in order to elicit a particular effect as referred to in the amylin agonist definition above is not known and difficult to discover. Further, substrate/receptor binding is unpredictable insofar that minor changes in substrate structure may result in an inactive substrate analogue due to the stereospecific requirements of receptor binding. Thus, the amylin art in general including receptor binding and mechanisms of action in particular is highly unpredictable.

The demonstration of efficacy with respect to a single peptidic amylin analogue regarding reducing or moderating a postprandial rise in plasma glucose is simply not commensurate in scope as compared to the scope of potential "amylin analogs" (both peptidic and nonpeptidic) which are within the scope of the presently claimed invention.

Accordingly, the specification discloses only limited examples that are neither representative of the claimed genus of amylin agonist compounds, nor is it clear that they represent a substantial portion of the claimed genus.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 24 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of amylin and specifically disclosed amylin analogues (e.g. specific species of proline containing amylin), the specification does not reasonably provide enablement for the use of amylin agonists which differ from anylin agonist analogues as defined and exemplified in the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use, the invention commensurate in scope with these claims.

There are many factors to consider when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any experimentation is "undue". These factors include, but are not limited to:

a. The breadth of the claims.
b. The nature of the invention
c. The state of the prior art;
d. The level of one of ordinary skill
e. The level of predictability in the art;
f. The amount of direction provided by the inventor;
g. The presence or absence of working examples;
h. The quantity of experimentation necessary needed to make or use the invention based on the disclosure;
See :*In re Wands* USPQ 2d 1400 (CAFC 1988):

(1-2) The breadth of the claims and the nature of the invention:

The present claims are directed to a method of reducing or moderating a postprandial rise in plasma glucose in a mammal comprising administering to said mammal an amylin or an amylin agonist (e.g. claim 24). Claims 38-40 encompass mammalian diabetics (e.g. types I or II).

Accordingly, the presently claimed invention is broadly directed to the therapeutic use of "amylin agonists" including "amylin agonist analogues" in any "subject". Use of

the term "amylin agonist" or "amylin agonist analogue" lacks metes and bounds as to what compounds are encompassed within the scope of the presently claimed invention. The specification on page 22 broadly defines an "amylin agonist" as "compounds which mimic the effects of amylin" without disclosing what effects are encompassed or what degree of mimicry is required in order to fit within the open-ended specification definition. It is noted that no structure limitation appears to limit what constitutes an "amylin agonist". Additionally, the term "amylin agonist analogue" is defined as "derivatives" of an amylin which act as "amylin agonists" by a hypothesized "direct/indirect" interaction with amyln receptors or other receptors to which amylin itself may interact. No disclosure of particular receptors or specific functions are disclosed. Accordingly, the amylin analogue definition fails to define the types of derivations of amylin encompassed by the definition nor is there any defined limits with regard to function which is necessary to satisfy the amylin agonist analogue. Accordingly, the skilled artisan could not possibly determine without undue experimentation which amylin or other compound might be effective for the desired purpose.

Further, method claims directed to "a subject" broadly encompass any animal possessing a GI tract; although the specification speak of only murine, canine and human species.

(3 and 5) *The state of the prior art and the level of predictability in the art:*

The pharmacological and pharmacokinetic properties of amylin have not been extensively characterize, and are therefore difficult to predict. For example, although amylin shares considerable sequence homology with CGRP's (and to a lesser degree

with insulin, relaxins and IGF) its physiological function appears to be distinct from that of the other peptides. Although some aspects of amylin function are accepted in the art, e.g. inhibition of glycogen syntheses and inhibition of gastric secretion, others are not well understood. Additionally, the receptors to which amylin directly or indirectly interacts with in order to elicit a particular effect as referred to in the amylin agonist definition above is not known and difficult to discover. Further, substrate/receptor binding is unpredictable insofar that minor changes in substrate structure may result in an inactive substrate analogue due to the stereospecific requirements of receptor binding. Thus, the amylin art in general including receptor binding and mechanisms of action in particular is highly unpredictable.

(4) *The level of one of ordinary skill in the art:*
The level of skill would be high, most likely at the Ph.D. level

(6-7) *The amount of direction provided by the inventor and the existence of working examples.*

The demonstration of efficacy with respect to a single amylin analogue regarding reducing or moderating a postprandial rise in plasma glucose is simply not commensurate in scope as compared to the scope of potential "amylin analogs" (both peptidic and nonpeptidic) which are within the scope of the presently claimed invention.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure:

The lack of guidance in the specification as to other non-amylin analogs and amylin derivatives which would be expected to be effective within the various thereapeutic claimed regimens, necessarily results in undue experimentation for one of ordinary skill wishing to practice the presently claimed invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 24 and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 24 and 38-40, use of the term "an amylin or amylin agonist" lacks metes and bounds as to what compounds will or will not infringe the claimed invention. The specification on page 22 broadly defines an "amylin agonist" as "compounds which mimic the effects of amylin" without discloses what effects are encompassed or what degree of mimicry is required in order to fit within the open-ended specification definition. It is noted that no structure limitation appears to define what constitutes an "amylin agonist". The term "amylin agonist analogue" is defined as "derivatives" of an amylin which act as "amylin agonists" by a hypothesized "direct/indirect" interaction with amyln receptors or other receptors to which amylin itself may interact. Accordingly, the amylin analogue definition fails to define the types of derivations of amylin encompassed by the definition nor is there any defined limits regard to function which is necessary to satisfy the amylin agonist analogue.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 24 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al. U.S. Pat. No.6,136,820 (10/2000: filed 12/90 or earlier).

The present claims are directed to a method of reducing or moderating a postprandial rise in plasma glucose in a mammal comprising administering to said mammal an amylin or an amylin agonist (e.g. claim 24). Claim 38 encompass mammalian diabetics (e.g. types I or II). "Amylin agonists" "refers to compounds which mimic the effects of amylin" (specification page 22, lines 3-5) . One amylin effect encompasses the ability of amylin to reduce post-prandial plasma glucose levels" (e.g. see specification page 21, lines 6-12).

Liu et al. Discloses and claims treating diabetes (e.g. in mammals) and postprandial hyperglycemia in diabetic individuals (e.g. mammals i.e. humans) by administering castanospermine (e.g. an "amylin agonist"). See specification (e.g. col. Bottom of column 1 to top of col. 2; examples; and patent claims, especially claims 1-2.

12. Claims 24 and 38-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al. U.S. Pat. No.6,136,820 (10/2000: filed 12/90 or earlier) or alternatively prima facie obvious in view of Meezan et al. U.S. Pat. No. 5,817,634 (10/98: filed 3/93) for purposes of defining the state of the prior art regarding "diabetes mellitus".

The present claims are directed to a method of reducing or moderating a postprandial rise in plasma glucose in a mammal comprising administering to said mammal an amylin or an amylin agonist (e.g. claim 24). Claim 38 encompass mammalian diabetics comprising diabetes mellitus types I or II (claims 39-40, respectively). "Amylin agonists" "refers to compounds which mimic the effects of amylin" (specification page 22, lines 3-5) . One amylin effect encompasses the ability of amylin to reduce post-prandial plasma glucose levels" (e.g. see specification page 21, lines 6-12).

Liu et al. Discloses and claims treating diabetes (e.g. in mammals) and treating (e.g. reducing or moderating) postprandial hyperglycemia in diabetic individuals (e.g. mammals i.e. humans) by administering castanospermine (e.g. an "amylin agonist"). See specification (e.g. col. bottom of column 1 to top of col. 2; examples; and patent claims, especially claims 1-2.

To the extent that Liu, although disclosing the treatment of diabetes mellitus and claiming the treatment of diabetes, fails to explicitly addresses diabetes mellitus types 1 and 2 the Meezan reference teaching is noted.

Meezan discloses (in its background section: col. 1) that "Diabetes mellitus consists of two (2) subtypes Type I and II both of which are "best characterized by hyperglycemia due to an absolute or relative lack of insulin".

Accordingly, in light of the Liu reference teaching of treating Diabetes mellitus and hyperglycemia, the treatment of Types I or II utilizing the Liu reference method would be immediately envisaged (e.g. anticipated) or in the alternative prima facie obvious to one of ordinary skill in the art at the time of applicant's invention. The rationale that a small reference genus can serve to either anticipate or alternatively render obvious a species contained therein

and the raising of a rejection pursuant to 102/103 as done in the present instance is consistent with both sound legal precedent and PTO practice. See e.g. *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978); MPEP 2131.02; MPEP 2144.08

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 24-30 and 38-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 (especially claims 32-35) of U.S. Patent No. 6,114,304 .

The present claims are directed to a method of *reducing or moderating* a postprandial rise in plasma glucose *in a mammal* comprising administering to said mammal an amylin or an amylin agonist (e.g. claim 24). Claims 38-40 and 57-59 encompass mammalian diabetics (e.g. types I or II). A preferred (e.g. elected) "amylin analog" is 25,28,29 Pro-h-amylin.

The patent claims are directed to a method of *treating* postprandial hyperglycemia *in a subject*" comprising administering the subject an amount of an amylin agonist of claims 1-12 (including 25,28,29 Pro-h-amylin)

The patent claimed method differs by not expressly teaching:

a. "treating" encompassing "reducing/moderating postprantial hyperglycemia; and

b. "subject" encompassing mammals such as humans.

However, the patent disclosure (e.g. bottom of col. 8) clearly demonstrates that the patented method of treating "inherently" reduces (e.g. moderates) postprandial hyperglycemia (e.g. see col. 8, lines 47-62) which is diabetic induced (e.g. see also col. 6, especially lines 8-21). Additionally, the patent disclosure examples specifically directed to (diabetic) human (e.g. mammalian) subjects (e.g. see Example 2: figures 1-8 clinical data on humans and dogs) and/or the patented preferred embodiment drawn to *human* amylin analogues (e.g. 25,28,29 Pro-h-amylin) would immediately envisage (e.g. anticipate) or alternatively render obvious the application (e.g. the selection of mammalian subjects) of the patented method to mammalian (diabetic) subjects to one of ordinary skill in the art.

14. Claims 24-30, 38, 40-57 and 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 (especially claims 1-12 and 18) of U.S. Patent No. 6,417,164 .

The present claims are directed to a method of *reducing or moderating* a postprandial rise in plasma glucose *in a mammal* comprising administering to said mammal an amylin or an amylin agonist (e.g. claim 24). Claims 38, 40, 57 and 59

encompass mammalian diabetics (e.g. type II). A preferred (e.g. elected) "amylin analog" is 25,28,29 Pro-h-amylin.

The patent claims are directed to a method for *reducing postprandial hyperglycemia* in a *non-insulin-taking Type II diabetic subject* comprising administering (single or divided doses) and amount (e.g. @ 0.05-10 micrograms/kg/day) of an amylin agonist, particularly 25,28,29 Pro-h-amylin.

The patented method clearly represents a "species" within the scope of the presently claimed generic insofar that the patented method is directed to a mammalian subject (e.g. a *non-insulin-taking Type II diabetic subject*) within the scope of the presently claimed invention. The patent claimed method directed to a non-insulin-taking Type II diabetic clearly encompasses human (e.g. mammalian) subjects as illustrated by the patent examples and/or the claimed use of human amylin analogs , particularly 25,28,29 Pro-h-amylin.

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
December 7, 2004